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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,639	10/17/2001	Michael J.P. Lawman	MOR-100D2	8705

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
981,639	LAWMAN et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 5/19/04.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 14-59 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☑ Claim(s) 14-59 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other____

Office Action Summary

The amendment of 5/19/04 has been entered. Claims 14-59 are pending and under examination.

The amendment has overcome the following bases of rejection stated in the office action of 11/28/03.

1) The rejection under 112, second para.

2) The 102 rejection over Englebienne et al.

3) The 102 rejection over Alva et al

4) The 102 rejection over Wong et al.

5) The 102 rejection over Ribi et al ('097). Ribi et al teach covalent binding, not entrapping, of the molecule having binding specificity for a target molecule to the polymer. They do not teach Fc receptors. They do not teach polyheteroaromatic or polyaromatic polymers.

6) The 102 rejection over Ribi et al ('810). Like comments apply as for the '097 reference.

7) The 102 rejection over Garnier et al. They teach covalent binding, not entrapping, of the molecule having binding specificity for a target molecule. They do not teach Fc receptors.

8) The 102 rejections over Taniguchi et al. They teach covalent binding, not entrapping, of the molecule having binding specificity for the target molecule. They do not teach Fc receptors.

9) The 102 rejection over Schneider et al. They do not teach entrapment of the molecule having binding specificity for the target molecule, nor do they teach Fc receptors.

10) The 102 rejection over Katoot et al. They do not teach Fc receptors.

11) The 102 rejection over Riviello et al. They do not teach Fc receptors.

12) The 102 rejection over Malmrose et al. There is no teaching of entrapment of the molecule having binding specificity for the target molecule; there is no teaching of Fc receptors.

13) The 102 rejection over McNeil et al. They do not show entrapment of the molecule having binding specificity for the target receptor. They do not show Fc receptors.

Claims 14-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter.

Claims 14 and 26 lack disclosure support for the concept of providing an immunomatrix having two polymers, wherein each of the two polymers entrap a different antibody. The only description of any matrix having two or more antibodies is in the para. spanning pages 11-12. Therein each of the different antibodies is provided in a different layer of the immunomatrix. What is recited in claims 14 and 26 is far broader,

since these claims recite nothing about the two-immuno polymers being in different layers of the immunomatrix.

Claims 14, 26, 44 and 56 have new matter by reciting that the horseradish peroxidase (HRP) and glucose oxidase (GOX) are "attached to or entrapped" within the polymer(s). The examiner finds no disclosure of enzymes that are "attached" (e.g. by covalent bonding) to the polymer. Rather these are "entrapped". See page 24, line 23. By reciting "attached" applicant is adding a new embodiment.

Claim 14, 26, 39 and 52 also have new matter by reciting that the antigen binding regions of the antibody are "presented external to the surface" of the immunopolymer. Page 10, lines 13-18 present the embodiment of binding antibodies to Fc receptors; therein nothing is stated absent the binding regions being "external to the surfaces".

In claims 17 and 49 "polythiophene" polymers constitute a new subgenus of broader scope than can be supported by the original disclosure. These must be limited to "alkyl substituted polythiophenes", as recited at page 11, line 7.

In claims 18 and 50 "naphthalene –doped" and "toluene doped" constitute new matter. Each of these was more specifically disclosed as naphthalene sulfonate or toluene sulfonate doped – e.g. page 13, lines 7 and 13; page 14, line 24; page 15, line 3; page 20, line 21; page 17, line 18. Where applicant recites these without "sulfonate" it appears to be merely a short hand reference to a matrix composition that can be seen to be constituted of naphthalene – sulfonate or toluene sulfonate, when one refers back to the method of preparation.

Also in claims 18 and 50, "toluene" is over by broad, since the "disclosure has more narrowly taught "p-toluene" – e.g. page 13, line 13.

For claims 21-22, 32-33, 46-47, and 58-59 there is no disclosure support (e.g. at page 10) for an Fc receptor, which specifically binds to IgG or to IgA.

For claims 23 ad 34 the term "sequentially oriented with respect to each other" lacks literal disclosure support. The examiner cannot determine where there may be any conceptual support, except in the paragraph spanning pages 11-12, wherein it is taught that different sequential layers of the polymer matrix may be provided with antibodies of different specificities. If such is the case, what is recited conveys something much broader, since claims 23 and 34 recite nothing about the two immunopolymers being in different layers of the matrix.

Claims 24-25 and 35-36 lack disclosure support since there has been no description of a single matrix, of two or more immunopolymers, that has one immunopolymer binding to an antigen not expressed on a rare cell, and another immunopolymer binding to an antigen that is expressed on a rare cell. The only disclosure of a matrix having multiple immunopolymers is in the para. spanning pages 11-12, in which case nothing is disclosed about antigens not expressed or expressed on rare cells.

For claims 26 and 37 and dependent claims 27-28, 30-36 and 39-47, there is no support for the new subgenus of polymers recited as "polyaromatic" polymers. Only the "polyphenol" recited in dependent claims 29 and 39 has disclosure support (e.g. page

15, line 24). A disclosure of a species within a subgenus of a properly described genus fails to support the subgenus. In re Smith 173 USPQ 679.

Claims 37 and 48, as well as dependent claims 38, 40, 43-44, 46-47, 49-51, 55-56 and 58-59 contain new matter by virtue of merely reciting the immunopolymer matrix as having an Fc receptor with no antibody bound thereto. The only disclosure of an immunomatrix having Fc receptors is at page 10, lines 13-18. While one reading this section might recognize that what is claimed is a disclosed intermediate for the preparation of an immunomatrix, there is no disclosure that this intermediate per se was contemplated as being the invention. Also, from the description of the invention at page 6, lines 10-24, one would have recognized that it is the immunopolymer with entrapped antibodies, not the intermediate with entrapped Fc receptors, that is what was contemplated as the invention.

Claims 22, 33, 47 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not disclosed how to make a matrix that has an Fc receptor that specifically binds the Fc portion of IgA.

The disclosure provides no reference to any patents or publications that teach such an Fc receptor. There is no disclosure of a commercial source. The examiner is not aware of any Fc receptor specific for IgA (Cruse et al). Enablement requires that all

starting materials be available to the public as of the filing date. Ex parte Moersch 104 USPQ 122.

Claims 14-37, 39, 41-42 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's disclosure has not enabled the making of an immunopolymer matrix having entrapped Fc receptors with antibody bound thereto such that the antigen binding region of the antibody is "presented external to the surface" of the conductive immunopolymer matrix.

Applicant has taught that receptors and/or antibodies become "trapped inside that polymer matrix as it is formed" (page 7, line 15); see similar language at page 8, line 1. The examiner finds no teaching anywhere of how entrapment of receptors and/or antibodies via polymerization of the conductive polymer results in any preferential orientation of these with respect to the surface of the polymer network forming the matrix. Applicant has taught no added ingredients and no physical parameters, which favor any particular orientation of the receptors and/or antibodies. From the disclosure the examiner envisions the conductive polymer as forming a cage that entraps the receptors and/or antibodies during the polymerization process. As the examiner sees it, the entrapment process per se does not lead to any particular orientation of the entrapped receptor and/or antibody. In the absence of any direction,

applicant is leaving it to others to conduct undue experimentation to find out what conditions result in the desired orientation/ presentation.

Claims 24-25 and 35-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

In the case of separating cells expressing a rare antigen (e.g. CD34 on stem cells) it is art conventional to positively select these (i.e. bind the stem cells to an anti-CD34 antibody and then release the bound cells. It is also conventional in such separations to negatively select cells that do not express the rare antigen (e.g. CD3, CD4, CD8 on T-cells; CD19, CD20 on B-cells); in negative selection methods, one binds cells with antibodies to the "non-rare" antigen and then discards these antibody bound cells, in order to enrich for the rare cells in the non-antibody bound fraction. The only description of any matrix having multiple types of antibodies is in the para. spanning pages 11-12. Therein all target selections are positive (i.e. cells of different layers are sequentially released). There is no teaching of how to use the device for the simultaneous use of negative selection and positive selection processes.

Claims 24-25 and 35-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

At the very least, if not an issue of a lack of teaching of how to use under 112, first paragraph, there is an issue of new matter, since the para. spanning pages 11-12 fails to mention any "rare" cell type (e.g. stem cells). See this action at page 5.

Prior art is applied to the pending claims as follows.

Claims 48-49, 51 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al (WO 96/04340).

Wallace et al (cited in previous office action) teach conductive polymers (e.g. of pyrrole or of thiophene, as disclosed at page 3, third para.) As far as the examiner can determine, the process of polymerization conducted by Wallace et al is no different from applicant's, in that the polymerization results in the entrapment of an added macromolecule, virus, or whole cell. See page 5, second full para. See page 18, second full para. Wallace et al disclose that cells such as monocytes or macrophages may be incorporated (page 22, penultimate line); such cells inherently bear Fc receptors (Cruse et al, page 110, col. 1). Comprising language of claims permits inclusion of the whole cell, rather than just the receptor, within the membrane; thus claims 48-49 are anticipated.

Claim 58 is included since Cruse et al teach that such cells (e.g. mononuclear phagocytes) leave Fc receptors for IgG,

Claim 51 is included from the teachings at page 3 and 17 regarding hydrophilic counterions.

Applicant's arguments filed on 5/19/04 have been fully considered but they are not persuasive. Applicant did not consider the full extent of Wallace et al's teachings.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David a Saunders

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PRIMARY EXAMINER
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Saunders/LR
August 11, 2004